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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) P054	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>MARCH 20, 2006</u></p> <p>Signature <u><i>Abby Bergella</i></u></p> <p>Typed or printed name <u>ABBY BERGHELLA</u></p>		Application Number <u>10/705,424</u>	Filed <u>11-10-03</u>
		First Named Inventor <u>FRANK LITVACK</u>	
		Art Unit <u>3138</u>	Examiner <u>PHAN, HIEU</u>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>38,699</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>		<p><u><i>Cindy A. Lynch</i></u> Signature <u>CINDY A. LYNCH</u> Typed or printed name <u>(650) 614-4131</u> Telephone number <u>MARCH 20, 2006</u> Date</p>	
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Dated: 3/20/06

Signature: Abby Berghella (Abby Berghella)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Frank Litvack, et al.

Application No.: 10/705,424

Filing Date: November 10, 2003

For: METHOD AND APPARATUS FOR TREATING  
VULNERABLE ARTEROSCLEROTIC  
PLAQUE

Art Unit: 3738

Examiner: Phan, Hieu

Attorney Ref. No.: P054

**PRE-APPEAL REQUEST FOR REVIEW**

**Mail Stop AF**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action dated October 19 2005, the response period extending through January 19 2006, which has been extended to March 19, 2006 Applicant requests a Pre-Appeal Brief Review in accordance with the guidelines set forth in the 12 July 2005 Official Gazette Notice (New Pre-Appeal Brief Conference Pilot Program, 1296 *Off. Gaz. Pat. Office* 67 (July 12, 2005); *see also* Extension of the Pilot Pre-Appeal Brief Conference Program, \_\_\_\_\_ *Off. Gaz. Pat. Office* \_\_\_\_\_ (January 10, 2006)) (collectively, "Notice"). Reconsideration of this application by a three Examiner panel is requested in view of the following remarks which identify the errors in facts, and the omission of essential elements required to establish a *prima facie* rejection.

**Summary of Final Office Action and Status of Application**

The Office Action again rejects Claims 1-14 as being anticipated by Doscher et al. (US 6,846,323) and Claims 15-26 as being anticipated by Castro et al. (US 6,616,765). In the Advisory Action dated February 23, 2006 the rejection has been maintained.

**Summary of the Claimed Invention**

As requested in the Notice, a summary of the claimed invention can be found in Applicant's Response filed 19 January 2006 ("Response"), in the third and fourth paragraphs appearing at page 2 thereof.

**Omission of Essential Elements Required for a *prima facie* case Necessitating Review**

In the Response filed 19 January 2006, Applicant detailed the feature of delivery of therapeutic agent primarily to a luminal side which is entirely missing from Doscher et al. In addition, Applicant detailed the features of primarily luminal release and therapeutic agent for stabilization of vulnerable plaque which are entirely missing from Castro. Therefore the factual showing that must be made in support of the rejection is that these elements are present in the cited references. The U.S. Patent and Trademark Office bears the burden of presenting evidence and reasoning why claimed subject matter allegedly is anticipated by the cited references.

Instead of presenting the evidence and reasoning required to establish a *prima facie* case, the Advisory Action only states:

Doscher et al. and Castro et al. both clearly disclose the treatment on a luminal side of a medical device (Doscher et al: col. 10, lines 63-67; Castro et al: col. 19, lines 1-30).

The passages cited in the Advisory Action merely teach that a coating can be on an inner surface of a device as well as an outer surface. This does not teach or suggest the *primarily luminal* delivery of agent as claimed.

Accordingly, the Office Action and Advisory Action fail to include essential elements to establish a *prima facie* case of anticipation, because it lacks at least:

an allegation of any teaching of primarily luminal delivery in the cited art; and

any allegation of any teaching of a therapeutic agent for stabilization of vulnerable plaque in Castro et al.

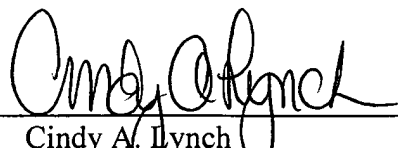
For at least the foregoing reasons, Applicant respectfully submits that the Office Action fails to include essential elements for establishing a *prima facie* case in support of the rejection of Claims 1-26 under 35 U.S.C. § 102(e).

**Conclusion**

Applicant respectfully submits that this application is in immediate and clear form for allowance based on the clear errors and omissions cited above. Accordingly, an early indication, via Notices of Allowance and Allowability, that all claims are allowed, is respectfully requested. Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application, the undersigned respectfully requests that she be contacted at the number indicated below.

An extension of time for two months is enclosed herewith. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to Deposit Account 50-3100.

Respectfully submitted,

By:   
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Registration No. 38,699

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Date: March 20, 2006